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Remarks

Claims 41 and 42 have been withdrawn from consideration as being directed to a non-elected invention. The Office Action asserts that the new claims are of a different species than previously presented because different fluorescing agents that were not previously claimed are now being claimed.

Allowable Subject Matter

Claims 12-14 are allowed.

New Rejections

35 U.S.C. §103(a)

Tingey et al. ('840) in view of Partin et al.

Claims 1, 3, 5 and 6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,667,840 to Tingey et al. ('840) in view of U.S. Patent No. 5,082,630 to Partin et al.

The Office Action asserts that "Tingey discloses the claimed invention except for the specific fluorescing agent being a fluorescein or a rhodamine. Partin et al. teach that a fluorescein and rhodamine are fluorescent dyes that have good absorption and fluorescent yield characteristics that provide high sensitivity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device, of Tingey with a rhodamine or a fluorescein fluorescent agent since these agents have good absorption and fluorescent yield characteristics."

Applicants traverse the rejection.

Claim 1 has been amended only for the purpose of correcting a typographical error. The word "and" was used twice in between the method steps.

Claim 1 is directed to a method for detecting the presence and uniformity of a lubricious coating on a medical device comprising the steps of preparing a mixture of at least one fluorescing agent which is a *xanthene*, a *triarylmethane* or mixture thereof and at least one lubricant, applying the mixture to the surface of a medical device to form a coating capable of exhibiting fluorescence subjecting the surface of the medical device to a source of energy capable

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of inducing a fluorescent emission, and observing the fluorescent emission to determine the location, uniformity or both of said lubricant.

Applicants submit that Tingey et al. '840 disclose a method for visualization of a polydimethylsiloxane lubricant coating on a surface of an article including dissolving a fluorescent agent into a lubricant, applying the fluorescencated lubricant to coat a surface of the article, irradiating the article with an electromagnetic radiation capable of inducing a fluorescent emission in the fluorescent agent and observing the fluorescent emission to detect the coverage of the lubricant on the surface of the article (Abstract, Summary and claim 1).

Polydimethylsiloxane is the only lubricant disclosed by Tingey et al.

Applicants further submit that Tingey et al. teach that "[i]n order to be effective in this application, the fluorescent agent must have a degree of solubility in polydimethylsiloxane. Polydimethylsiloxane is an extremely hydrophobic material, and most fluorescent dyes are virtually insoluble in it." Column 4, lines 33-35. For this reason, the use of most fluorescent dyes in the polydimethylsiloxane lubricant of Tingey et al. is *not* prima facie obvious.

Tingey et al. teach that the preferred dyes are 7-diethylamino-4-trifluoromethyl-2H-1-benzopyran-2-one, commonly known as coumarin 481, 7-dimethylamino-4-trifluoromethyl-2H-1-benzopyran-2-one, commonly known as coumarin 485, mixtures thereof and the like. These dyes are made by Exiton, Dayton, Ohio and available from Eastman Chemical, Kingsport, Tenn. See col. 4, lines 56-63. Thus, the only dyes suggested by Tingey et al. as having a degree of solubility in the polydimethylsiloxane are specific coumarin dyes.

Applicants submit that Partin et al. disclose a portable fiber optic detector that senses the presence of specific target chemicals in air or a gas by exchanging the target chemical for a fluorescently-tagged antigen that is bound to an antibody which is in turn attached to an optical fiber (Abstract). A fluorescent compound is affixed to a reactive site on the antigen. (See claim 1). Replacing the fluorescently-tagged antigen reduces the fluorescence so that a photon sensing detector records the reduced light level and activates an appropriate alarm or indicator (Abstract).

Partin et al. disclose that the fluorescent compound may be selected from fluorescein and rhodamine (claim 6 and Summary of the Invention, last paragraph), which are both xanthene type dyes. See page 7 of the present specification.

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Applicants submit that there would be no motivation to combine the fluorescent compounds, fluorescein and rhodamine, with the polydimethylsiloxane lubricant of Tingey et al. because Tingey et al. suggest only specific coumarin dyes for use with polydimethylsiloxane, which Tingey et al. describe as being extremely hydrophobic. There is no suggestion by Tingey et al. that fluorescein and rhodamine could be employed in combination with a polydimethylsiloxane lubricant, and there is no reason to expect from this combination of references, that such dyes would have the degree of solubility in polydimethylsiloxane expressly required by Tingey et al.

When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. *In re Geiger*, 815 F.2d 686, 688 (2 USPQ2d 1276) (Fed. Cir. 1987). Although the suggestion to combine references may flow from the nature of the problem, *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (37 USPQ2d 1626) (Fed. Cir. 1996), the suggestion more often comes from the teachings of the pertinent references, *In re Sernaker*, 702 F.2d 989, 994 (217 USPQ 1) (Fed. Cir. 1983) (citing *Akamai Technologies Inc. v. Cable & Wireless Internet Services Inc.*, 68 USPQ2d 1186, 1993 (Fed. Cir. 2003)).

Applicants submit that the combination of Tingey et al. '840 and Partin et al. '630 does not suggest to one of skill in the art that fluorescein or rhodamine dyes may be employed in combination with a polydimethylsiloxane lubricant, nor does the combination provide motivation to do so.

Applicants therefore submit that claim 1 is patentable over the combination of Tingey et al. '840 and Partin et al.

Claims 3, 5 and 6 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 1, 3, 5 and 6 under 35 U.S.C. §103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al., U.S. Patent No. 5,082,630.

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*Tingey et al. ('840) in view of Partin et al.
and further in view of Peyman et al.*

Claims 4, 39 and 40 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al., as applied above, and further in view of U.S. Patent No. 6,346,689 to Peyman et al.

The Office Action asserts that "Tingey, as modified, discloses the claimed invention except for the specific fluorescing agent being carboxyfluorescein. Peyman teaches that carboxyfluorescein is a hydrophilic derivative of fluorescein that is well known in the art to be used in applications to blood vessels that require fluorescent agents (Column 1, lines 42-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Tingey, as modified, with the fluorescing agent of a carboxyfluorescein since it is well known to be used in the surgical arts."

Claim 1 has been discussed above.

Tingey et al. '840 and Partin et al. '630 have been discussed above.

Applicants submit that claim 1 is patentable over Tingey et al. and Partin et al. for the reasons discussed above. There is no motivation to combine the fluorescein and rhodamine compounds of Partin et al. with the hydrophobic lubricant of Tingey et al. as Tingey et al. teach that solubility in the hydrophobic polydimethylsiloxane lubricant is difficult, but necessary, and that the preferred dyes are specific coumarin dyes, not fluorescein or rhodamine.

Applicants submit that there is even less motivation to combine the carboxyfluorescein dye, expressly disclosed as a *hydrophilic* derivative of fluorescein in Peyman et al. with the hydrophobic lubricant of Tingey et al., than there is to combine the fluorescein or rhodamine compounds of Partin et al. with the hydrophobic lubricant of Tingey et al. A known hydrophilic derivative of fluorescein would be considered to be excluded by the degree of solubility in the hydrophobic polydimethylsiloxane lubricant required by Tingey et al.

Applicants submit that claim 1 is therefore patentable over the combination of Tingey et al. '840, Partin et al. and Peyman et al.

Claims 4 and 39 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable over the combination of Tingey et al. '840, Partin et al. and Peyman et al.

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Independent claim 40 has been amended and is directed to a method for detecting the presence and uniformity of a lubricious coating on a medical device, the method including the steps of comprising the steps of preparing a mixture of at least one *hydrophilic* fluorescing agent and mixtures thereof and at least one *hydrophobic* lubricant, applying the mixture to the surface of a medical device to form a coating capable of exhibiting fluorescence, subjecting the surface of the medical device to a source of energy capable of inducing a fluorescent emission, and observing the fluorescent emission to determine the location, uniformity or both of said lubricant.

Tingey et al., Partin et al., and Peyman et al. have been discussed above.

Applicants submit that Tingey et al. teach that in order to be effective, the fluorescent agent must have a degree of solubility in polydimethylsiloxane. Tingey et al. further describe the polydimethylsiloxane as being extremely hydrophobic, and conclude that most fluorescent dyes are virtually insoluble in it (col. 4, lines 34-35).

Applicants submit that Tingey et al. do not disclose that hydrophilic fluorescing agents would have the degree of solubility as specified by Tingey et al., necessary to employ in combination with the hydrophobic polydimethylsiloxane lubricant of Tingey et al.

Tingey et al. only disclose specific coumarin dyes as having the degree of solubility necessary.

Thus, again, there is no motivation to combine the fluorescein or rhodamine dyes of either Partin et al. or Peyman et al. with the polydimethylsiloxane lubricant of Tingey et al. because there is not reason to expect that they would have the degree of solubility necessary.

Certainly, a hydrophilic fluorescing agent, as recited in claim 40, would not have the degree of solubility necessary in the extremely hydrophobic polydimethylsiloxane. See column 1, lines 32-35 of Tingey et al.

As there is no motivation to combine the fluorescein and rhodamine dyes of Partin et al. or the hydrophilic fluorescein derivatives of Peyman et al., with the hydrophobic lubricant of Tingey et al., claim 40, which recites a hydrophilic fluorescing agent in combination with a hydrophobic lubricant, is therefore patentable over this combination of references.

Applicants respectfully request withdrawal of the rejection of claims 4, 39 and 40 under 35 U.S.C. §103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al., as applied above, and further in view of U.S. Patent No. 6,346,689 to Peyman et al.

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*Tingey et al. ('840) in view of Partin et al.
and further in view of Anderson et al.*

Claim 7 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al. '630, as applied above, and further in view of U.S. Patent No. 6,254,634 to Anderson et al.

The Office Action asserts that "Tingey, as modified discloses the claimed invention except for the use of a lubricant in combination with a crosslinkable silicone, but that Anderson teaches that an intermediate layer of crosslinkable silicone is provided with a coating in order to improve the performance or durability of the coating (Column 3, lines 41-62 and Column 5, lines 42-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Tingey, as modified, with the crosslinkable silicone in order to improve the durability of the coating on the medical device."

Applicants traverse the rejection.

Tingey et al. and Partin et al. have been discussed above.

Applicants submit that claim 1 is patentable over this combination because there is no motivation to combine Partin et al. with Tingey et al. as there is no suggestion that the fluorescein and rhodamine dyes of Partin et al. would have the degree of solubility required by Tingey et al. in the hydrophobic polydimethylsiloxane lubricant disclosed therein.

Adding a crosslinkable silicone to polydimethylsiloxane, does not change the lack of motivation to combine Partin et al. with Tingey et al.

Consequently, claim 1 is patentable over Tingey et al., Partin et al. and Anderson et al.

Claim 7 depends from claim 1 and is patentable for at least the reasons that claim 1 is patentable.

Applicants respectfully request withdrawal of the rejection of claim 7 under 35 U.S.C. §103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al. '630, as applied above, and further in view of U.S. Patent No. 6,254,634 to Anderson et al.

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*Tingey et al. ('840) in view of Partin et al.
and further in view of Spielvogel*

Claims 8-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al. '630, as applied above, and further in view of U.S. Patent No. 5,266,359 to Spielvogel.

The Office Action asserts that "Tingey, as modified, discloses the claimed invention except for the mixture further comprising a surfactant. Spielvogel teaches that a surfactant may be added to a medical device in order to improve the lubriciousness of the device (Column 2 lines 49-56 and Column 4 lines 38-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Tingey with the surfactant of Spielvogel in order to improve the lubricity of the device."

Tingey et al. '840 and Partin et al. '630 have been discussed above.

Applicants submit that claim 1 is patentable over Tingey et al. and Partin et al. for the reasons discussed above.

Spielvogel is directed to a lubricating composition including an emulsion of a noncuring polysiloxane, a surfactant and water.

Applicant believes that Spielvogel has been misunderstood by the examiner as the purpose of the surfactant described employed in Spielvogel is for emulsification, not for improving the lubriciousness of the lubricating composition.

As neither Tingey et al. nor Partin et al. are concerned with emulsification, there would be no reason to combine Spielvogel with Tingey et al. and Partin et al.

Claim 1 is patentable over this combination of references. Claims 8-11 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 8-11 under 35 U.S.C. §103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al. '630, as applied above, and further in view of U.S. Patent No. 5,266,359 to Spielvogel.

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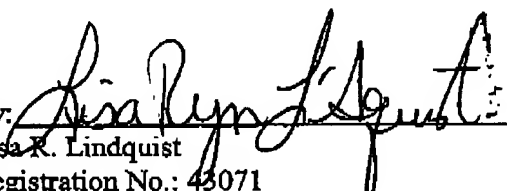
CONCLUSION

Claims 1, 3-14, 39 and 40 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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